CLAIMS

What is claimed is:

1. A biocompatible drug release matrix for a medical device comprising:

a biocompatible polymer matrix; and

a drug incorporated into the biocompatible polymer matrix,

wherein the biocompatible polymer matrix is co-solubilized with the drug in a solvent to form a solution and the solvent is evaporated from the solution.

2. The biocompatible drug release matrix of claim 1 wherein the drug has antibiotic properties and anti-proliferative properties.

3. The biocompatible drug release matrix of claim 1 wherein the drug is an analogue related to the quinone-containing alkylating agents of a mitomycin family.

4. The biocompatible drug release matrix of claim 1 wherein the drug is mitomycin C.

5. The biocompatible drug release matrix of claim 1 wherein a ratio of the weight of the biocompatible polymer matrix and the drug is about 4 to about 1.

6. The biocompatible drug release matrix of claim 1 wherein the solvent is selected from the group consisting of water, saline, tetrahydrofuran, methanol, acetone, butyl acetate, cyclohexane, carbon tetrachloride, ether, chloroform, benzene, ethanol, toluene, dimethyl sulfoxide, petroleum ethers, other hydrocarbons and other organic solvents.

7. The biocompatible drug release matrix of claim 1 wherein the biocompatible polymer matrix comprises polyvinyl pyrrolidone with an at least one isocyanate.

8. The biocompatible drug release matrix of claim 1 wherein the biocompatible polymer matrix comprises a mixture of hydrophilic and hydrophobic polymers selected from

the group consisting of polyurethanes, polyvinyl pyrrolidone, poly methyl methracrylate (PMMA), hydroxyetyl methacrylate and cellulose esters.

9. The biocompatible drug release matrix of claim 1 wherein the biocompatible polymer matrix comprises an erodible polymer.

10. The biocompatible drug release matrix of claim 9 wherein the erodible polymer is selected from the group consisting of polyactide, polyactide with glycolide, polyester-amides, polyurethanes, poly(ethylene-urethane), poly(ester-urethane) and poly(ether-polyester-urethane), amino-acid based polyurethanes, polycaprolactone based polyurethanes, polyurethanes synthesized from poly(butylene succinate) polyol, poly(ethylene glycol), and 4,4'-methylenebis(cyclohexyl isocyanate), fat, carbohydrates and protein compounds.

11. The biocompatible drug release matrix of claim 1 wherein the biocompatible polymer matrix comprises parylene and derivatives of parylene.

12. The biocompatible drug release matrix of claim 1 wherein the biocompatible polymer matrix comprises polybutylmethacrylate and polyethylenevinylacetate.

13. The biocompatible drug release matrix of claim 12 wherein the concentrations of polybutylmethacrylate and polyethylenevinylacetate are approximately equal.

14. The biocompatible drug release matrix of claim 1 wherein the biocompatible polymer matrix comprises a thermoplastic polyurethane elastomer.

15. The biocompatible drug release matrix of claim 1 wherein the biocompatible polymer matrix is selected from the group consisting of hybrid polymers, composites and polymer blends, acrylate terpolymers, tri-block polymers, polyethylene vinyl-acetate methacrylic tri-block terpolymer, ethyl-vinyl acetate, polyethyl vinyl-acetate, polybutyl methacrylic acid and polyethyl vinyl-acetate blends, polyurethanes and polyurethane-polycarbonate blends, silicone-urethane copolymers, polyvinyl pyrrolidone, polyester resins and parylene.

16. A biocompatible implantable medical device for delivering a drug to a treatment area in a vasculature of a body comprising:

a tubular body having a proximal end, a distal end and a longitudinal axis therebetween;

a proximal end band at the proximal end of the tubular body, a distal end band at the distal end of the tubular body and a plurality of intermediate bands between the proximal end band and the distal end band;

a plurality of circumferential rows of links engaging the proximal end band, the plurality of intermediate bands and the distal end band to form the tubular body; and

an elution layer comprising a biocompatible drug release matrix applied to the surface of the biocompatible implantable medical device having a biocompatible polymer matrix solubilized with the drug in a solvent to form a solution and the solvent is evaporated, wherein the drug is released from the biocompatible drug release matrix after implantation of the biocompatible implantable medical device to prevent restenosis.

17. The biocompatible implantable medical device of claim 16 further comprising a primer layer surrounding a strut of the biocompatible implantable medical device.

18. The biocompatible implantable medical device of claim 16 further comprising a burst control layer surrounding the elution layer.

19. The biocompatible implantable medical device of claim 16 wherein the biocompatible implantable medical device is a stent.

20. The biocompatible implantable medical device of claim 16 wherein the biocompatible implantable medical device is selected from the group consisting of a catheter, a vascular prosthesis and an intravenous canule.

21. The biocompatible implantable medical device of claim 16 wherein the biocompatible polymer matrix comprises polyvinyl pyrrolidone with an at least one isocyanate.

22. The biocompatible implantable medical device of claim 16 wherein the biocompatible polymer matrix comprises a mixture of hydrophilic and hydrophobic polymers selected from the group consisting of polyurethanes, polyvinyl pyrrolidone, poly methyl methracrylate (PMMA), hydroxyetyl methacrylate and cellulose esters.

23. The biocompatible implantable medical device of claim 16 wherein the biocompatible polymer matrix comprises parylene and derivatives of parylene.

24. The biocompatible implantable medical device of claim 16 wherein the biocompatible polymer matrix comprises polybutylmethacrylate and polyethylenevinyl acetate.

25. The biocompatible implantable medical device of claim 24 wherein the concentrations of polybutylmethacrylate and polyethylenevinylacetate are approximately equal.

26. The biocompatible implantable medical device of claim 16 wherein the biocompatible polymer matrix comprises an erodible polymer.

27. The biocompatible implantable medical device of claim 26 wherein the erodible polymer is selected from the group consisting of polyactide, polyactide with glycolide, polyester-amides, polyurethanes, poly(ethylene-urethane), poly(ester-urethane) and poly(ether-polyester-urethane), amino-acid based polyurethanes, polycaprolactone based polyurethanes, polyurethanes synthesized from poly(butylene succinate) polyol, poly(ethylene glycol), and 4,4'-methylenebis(cyclohexyl isocyanate), fat, carbohydrates and protein compounds.

28. The biocompatible implantable medical device of claim 16 wherein the biocompatible polymer matrix comprises a thermoplastic polyurethane elastomer.

29. The biocompatible implantable medical device of claim 16 wherein the elution layer releases the drug at a rate sufficient to maintain tissue level concentrations of the drug from about 0.01 micrograms per milliliter to about 25 micrograms per milliliter of the

surrounding tissue for at least two weeks after implantation of the biocompatible implantable medical device.

30. The biocompatible implantable medical device of claim 16 wherein the biocompatible polymer matrix is selected from the group consisting of hybrid polymers, composites and polymer blends, acrylate terpolymers, tri-block polymers, polyethylene vinyl-acetate methacrylic tri-block terpolymer, ethyl-vinyl acetate, polyethyl vinyl-acetate, polybutyl methacrylic acid and polyethyl vinyl-acetate blends, polyurethanes and polyurethane-polycarbonate blends, silicone-urethane copolymers, polyvinyl pyrrolidone, polyester resins and parylene.

31. The biocompatible implantable medical device of claim 16 wherein the biocompatible polymer matrix and the drug are applied to the biocompatible implantable medical device by a chemical vapor deposition process.

32. The biocompatible implantable medical device of claim 16 wherein the biocompatible polymer matrix and the drug are applied to the biocompatible implantable medical device by a process selected from the group consisting of brush coating, dip coating, spray coating, electrostatic deposition, ion sputtering, vapor deposition, pulsed chemical vapor deposition, controlled vacuum ultrasonic nanodrop spray deposition, flash evaporation and surface polymerization and polymer multi-layer deposition.

33. The biocompatible implantable medical device of claim 16 wherein the drug has antibiotic properties and anti-proliferative properties.

34. The biocompatible implantable medical device of claim 16 wherein the drug is mitomycin C.

35. The biocompatible implantable medical device of claim 16 wherein the drug is an analogue related to the quinone-containing alkylating agents of a mitomycin family.

36. The biocompatible implantable medical device of claim 16 wherein a total dosage of about 10 micrograms of the drug per millimeter of a length of the biocompatible

implantable medical device is coated on the biocompatible implantable medical device.

37. The biocompatible implantable medical device of claim 16 wherein a total dosage of about 0.5 micrograms to about 50 micrograms of the drug per millimeter of a length of the biocompatible implantable medical device is coated on the biocompatible implantable medical device.

38. The biocompatible implantable medical device of claim 16 wherein the biocompatible drug release matrix coated on the surface of the biocompatible implantable medical device is between about 5 microns to about 120 microns thick.

39. The biocompatible implantable medical device of claim 16 wherein an initial dose of between about 10 percent and about 60 percent of the drug is delivered to the vasculature in the first few days after implantation of the biocompatible implantable medical device.

40. The biocompatible implantable medical device of claim 16 wherein initially the drug is released from the biocompatible polymer matrix at a faster rate followed by a release of the drug at a slower rate.

41. A method of inhibiting the growth of smooth muscle cells to inhibit restenosis comprising:

providing a biocompatible implantable medical device;

preparing a biocompatible polymer matrix;

co-solubilizing the biocompatible polymer matrix with a drug in a solvent to form a biocompatible drug release matrix;

applying the biocompatible drug release matrix to the biocompatible implantable medical device to form an elution layer of the biocompatible drug release matrix on the biocompatible implantable medical device;

allowing the solvent to evaporate; and

implanting the biocompatible implantable medical device into a vasculature of a body.

42. The method of claim 41 further comprising engaging the biocompatible implantable medical device onto a balloon of a balloon catheter.

43. The method of claim 41 further comprising delivering a balloon catheter with the biocompatible implantable medical device engaged onto a balloon of the balloon catheter into the vasculature.

44. The method of claim 41 further comprising inflating a balloon of a balloon catheter to increase a diameter of the biocompatible implantable medical device engaged onto the balloon of the balloon catheter.

45. The method of claim 41 wherein the drug has antibiotic properties and anti-proliferative properties.

46. The method of claim 41 wherein the drug is an analogue related to the quinone-containing alkylating agents of a mitomycin family.

47. The method of claim 41 wherein the drug is mitomycin C.

48. The method of claim 41 wherein the biocompatible polymer matrix comprises polyvinyl pyrrolidone with an at least one isocyanate.

49. The method of claim 41 wherein the biocompatible polymer matrix comprises a mixture of hydrophilic and hydrophobic polymers selected from the group consisting of polyurethanes, polyvinyl pyrrolidone, poly methyl methracrylate (PMMA), hydroxyetyl methacrylate and cellulose esters.

50. The method of claim 41 wherein the biocompatible polymer matrix comprises an erodible polymer.

51. The method of claim 41 wherein the erodible polymer is selected from the group consisting of polyactide, polyactide with glycolide, polyester-amides, polyurethanes, poly(ethylene-urethane), poly(ester-urethane) and poly(ether-polyester-urethane), amino-acid based polyurethanes, polycaprolactone based polyurethanes, polyurethanes synthesized from poly(butylene succinate) polyol, poly(ethylene glycol), and 4,4'-methylenebis(cyclohexyl isocyanate, fat, carbohydrates and protein compounds.

52. The method of claim 41 wherein the biocompatible polymer matrix comprises parylene and derivatives of parylene.

53. The method of claim 41 wherein the biocompatible polymer matrix comprises polybutylmethacrylate and polyethylenevinyl acetate.

54. The method of claim 41 wherein the concentrations of polybutylmethacrylate and polyethylenevinylacetate are approximately equal.

55. The method of claim 41 wherein the biocompatible polymer matrix comprises a thermoplastic polyurethane elastomer.

56. The method of claim 41 further comprising releasing the drug at a rate sufficient to maintain a tissue level concentration of the drug from about 0.01 micrograms per milliliter to about 25 micrograms per milliliter of the surrounding tissue for at least two weeks after implantation of the biocompatible implantable medical device.

57. The method of claim 41 wherein the biocompatible polymer matrix is selected from the group consisting of hybrid polymers, composites and polymer blends, acrylate terpolymers, tri-block polymers, polyethylene vinyl-acetate methacrylic tri-block terpolymer, ethyl-vinyl acetate, polyethyl vinyl-acetate, polybutyl methacrylic acid and polyethyl vinyl-acetate blends, polyurethanes and polyurethane-polycarbonate blends, silicone-urethane copolymers, polyvinyl pyrrolidone, polyester resins and parylene.

58. The method of claim 41 wherein a ratio of the weight of the biocompatible polymer matrix and the drug is about 4 to 1.

59. The method of claim 41 wherein the solvent is selected from the group consisting of water, saline, tetrahydrofuran, methanol, acetone, butyl acetate, cyclohexane, carbon tetrachloride, ether, benzene, ethanol, toluene, chloroform, dimethyl sulfoxide, petroleum ethers, other hydrocarbons and other organic solvents.

60. The method of claim 41 wherein the biocompatible implantable medical device is a stent.

61. The method of claim 41 wherein the biocompatible implantable medical device is selected from the group consisting of a catheter, a vascular prosthesis and an intravenous canule.

62. The method of claim 41 wherein the solution is deposited onto the biocompatible implantable medical device by a chemical vapor deposition process.

63. The method of claim 41 wherein the biocompatible polymer matrix and the drug are applied to the biocompatible implantable medical device by a process selected from the group consisting of brush coating, dip coating, spray coating, electrostatic deposition, ion sputtering, vapor deposition, pulsed chemical vapor deposition, controlled vacuum ultrasonic nanodrop spray deposition, flash evaporation and surface polymerization and polymer multi-layer deposition.

64. The method of claim 41 further comprising applying a primer layer on the biocompatible implantable medical device.

65. The method of claim 41 further comprising applying a burst control layer on the elution layer.

66. The method of claim 41 further comprising coating the biocompatible implantable medical device with a total dosage of about 10 micrograms of the drug per millimeter of a length of the biocompatible implantable medical device.

67. The method of claim 41 further comprising coating the biocompatible implantable medical device with a total dosage of about 0.5 micrograms to about 50 micrograms of the drug per millimeter of a length of the biocompatible implantable medical device.

68. The method of claim 41 further comprising coating the biocompatible drug release matrix on the surface of the biocompatible implantable medical device with a thickness between about 5 microns to about 120 microns.

69. The method of claim 41 further comprising delivering an initial dose of between about 10 percent to about 60 percent of the drug to the vasculature in the first few days after implantation of the biocompatible implantable medical device.

70. The method of claim 41 further comprising delivering at least a portion of a remainder of the drug at a slower rate than an initial dose of the drug.

71. A method of inhibiting the proliferation of smooth muscle cells after a stent implantation comprising:

providing a stent;

preparing a biocompatible polymer matrix;

co-solubilizing the biocompatible polymer matrix with a drug in a solvent to form a solution;

applying the solution onto the stent to form an elution layer of a biocompatible drug release matrix on the biocompatible implantable medical device;

allowing the solvent to evaporate;

engaging the stent onto a balloon of a balloon catheter;

delivering the balloon catheter with the stent engaged onto the balloon of the balloon catheter into a vasculature of a body to a treatment site; and

inflating the balloon of the balloon catheter to increase a diameter of the stent to implant the stent.

72. The method of claim 71 further comprising deflating the balloon and removing the balloon catheter with the balloon from the body.

73. The method of claim 71 wherein the drug is mitomycin C.

74. The method of claim 71 wherein the drug is an analogue related to the quinone-containing alkylating agents of a mitomycin family.

75. The method of claim 71 wherein the solvent is selected from the group consisting of water, saline, tetrahydrofuran, methanol, acetone, butyl acetate, cyclohexane, carbon tetrachloride, ether, benzene, ethanol, toluene, chloroform, dimethyl sulfoxide, petroleum ethers, other hydrocarbons and other organic solvents.

76. The method of claim 71 further comprising depositing the solution onto the biocompatible implantable medical device by a chemical vapor deposition process.

77. The method of claim 71 further comprising delivering an initial dose of between about 10 percent to about 60 percent of the drug to the vasculature in the first few days after implantation of the stent.

78. A biocompatible drug release matrix for a medical device comprising:

a biocompatible drug eluting matrix; and

a drug incorporated into the biocompatible drug eluting matrix,

wherein the drug is an analogue related to the quinone-containing alkylating agents of a mitomycin family.

79. The biocompatible drug release matrix of claim 78 wherein the drug is mitomycin C.

80. The biocompatible drug release matrix of claim 78 wherein the biocompatible drug eluting matrix releases the drug at a rate sufficient to maintain tissue level concentrations of the drug from about 0.01 micrograms per milliliter to about 25 micrograms per milliliter of the surrounding tissue for at least two weeks after implantation of the medical device.

81. The biocompatible drug release matrix of claim 78 wherein the biocompatible drug eluting matrix has a concentration of the drug between about 0.1 micrograms and about 101 micrograms per millimeter of medical device length.

82. The biocompatible drug release matrix of claim 78 wherein the biocompatible drug eluting matrix has a concentration of the drug between about 0.02 $\mu g/mm^2$ and about 2.5 $\mu g/mm^2$ per medical device surface area.

83. The biocompatible drug release matrix of claim 78 wherein the medical device is coated with a total dosage of about 10 micrograms of the drug per millimeter length of the medical device.

84. The biocompatible drug release matrix of claim 78 wherein the medical device is coated with a total dosage of about 0.5 micrograms to about 50 micrograms of the drug per millimeter length of the medical device.

85. The biocompatible drug release matrix of claim 78 wherein an initial dose of between about 10 percent to about 60 percent of the drug is delivered to the tissue in the first few days after implantation of the medical device.

86. The biocompatible drug release matrix of claim 78 wherein at least a portion of a remainder of the drug is delivered at a slower rate than an initial dose of the drug.

87. The biocompatible drug release matrix of claim 78 further comprising a burst control layer to reduce the rate of diffusion of the drug from the biocompatible drug release matrix.

88. The biocompatible drug release matrix of claim 78 wherein mitomycin C is eluted from the biocompatible drug release matrix at a controlled rate.

89. The biocompatible drug release matrix of claim 78 wherein the biocompatible drug release matrix is incorporated within a vascular prosthesis.

90. The biocompatible drug release matrix of claim 78 wherein the biocompatible drug release matrix comprises a coating applied to the surface of a vascular prosthesis.

91. The biocompatible drug release matrix of claim 78 wherein the biocompatible drug release matrix comprises a film which covers a vascular prosthesis.

92. The biocompatible drug release matrix of claim 78 wherein the biocompatible drug release matrix is co-solubilized with the drug in a solvent to form a solution and the solvent is evaporated from the solution.

93. The biocompatible drug release matrix of claim 78 further comprising polyvinyl pyrrolidone with an at least one isocyanate.

94. The biocompatible drug release matrix of claim 78 further comprising an erodible polymer.

95. The biocompatible drug release matrix of claim 78 wherein the erodible polymer is selected from the group consisting of polyactide, polyactide with glycolide, polyester-amides, polyurethanes, poly(ethylene-urethane), poly(ester-urethane) and poly(ether-polyester-urethane), amino-acid based polyurethanes, polycaprolactone based polyurethanes, polyurethanes synthesized from poly(butylene succinate) polyol, poly(ethylene glycol), and 4,4'-methylenebis(cyclohexyl isocyanate), fat, carbohydrates and protein compounds.

96. A method of inhibiting restenosis comprising:

providing a medical device;

applying a biocompatible drug eluting matrix comprising a biocompatible polymer matrix incorporating an analogue related to the quinone-containing alkylating agents of a mitomycin family to the medical device; and

implanting the biocompatible implantable medical device into a vessel to elute the analogue related to the quinone-containing alkylating agents of a mitomycin family.

97. The method of claim 96 further comprising applying a primer layer on the medical device.

98. The method of claim 96 further comprising applying a burst control layer on the biocompatible drug eluting matrix.

99. The method of claim 96 further comprising coating the medical device with a total dosage of about 10 micrograms of the drug per millimeter of a length of the medical device.

100. The method of claim 96 further comprising coating the medical device with a total dosage of about 0.1 micrograms to about 100 micrograms of the drug per millimeter of a length of the medical device.

101. The method of claim 96 further comprising coating the biocompatible drug release matrix on the surface of the medical device with a thickness between about 5 microns to about 120 microns.

102. The method of claim 96 further comprising delivering an initial dose of between about 10 percent to about 60 percent of the drug to the tissue in the first few days after implantation of the medical device.

103. The method of claim 96 further comprising delivering at least a portion of a remainder of the drug at a slower rate than initial dose of the drug.

104. The method of claim 96 further comprising releasing the drug at a rate sufficient to maintain a tissue level concentration of the drug from about 0.01 micrograms per milliliter to about 25 micrograms per milliliter of the surrounding tissue for at least two weeks after implantation of the medical device.